

ERS, a sample of which is deposited at the ECACC under accession no. 99011475, of at least 80% in a plaque reduction assay.

25. The vaccine of Claim 5 wherein the avian reovirus is able to induce antiserum in an animal, which antiserum causes a reduction of the plaques formed by avian reovirus ERS, a sample of which is deposited at the ECACC under accession no. 99011475, of at least 90% in a plaque reduction assay.

Please amend the Claims as follows:

14. (Twice Amended) A vaccine comprising an avian reovirus which is avian reovirus ERS, a sample of which is deposited at the ECACC under accession no. 99011475, and a pharmaceutically acceptable carrier or diluent.

[An avian reovirus which is avian reovirus ERS, a sample of which is deposited at the ECACC under accession no. 99011475 and further which positively reacts with polyclonal avian reovirus antiserum but not with monoclonal antibodies identified by accessions nos. 99011472, 99011473 and 99011474, samples of which are deposited at the ECACC.]

### III. Remarks

Applicants have noticed an error in Claim amendments, such that non-elected subject matter has been claimed in Claim 14. Applicants have corrected this typographical error by amendment. However, such amendment only incorporates previously unincorporated subject matter that was unincorporated by mistake. This

amendment was not made for any reason related to patent ability under 35 USC §§101, 102, 103, and/or 112. No estoppel should result from this amendment.

A. 35 USC §112, ¶2

Claims 5-9 stand rejected under 35 USC 112, 2<sup>nd</sup> ¶, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. The Examiner contends that the claims are vague and indefinite for failing to clearly set forth the salient features of the claimed invention. The Examiner's contention is based upon whether Applicants' claimed invention encompasses vaccine stock comprising a virus having the ECACC designation of 9901475 or whether that designation refers simply to the reference virus employed in the plaque reduction assays. Applicants' invention, as claimed in Claim 5 and as disclosed on page 4, lines 15-20 of the Detailed Description, positively claims avian reoviruses of the antigenic class of avian reoviruses, wherein the avian reovirus is able to induce antiserum in an animal, which antiserum causes a reduction of the plaques formed by avian reovirus ERS, a sample of which is deposited at the ECACC under accession no. 99011475, of at least 75% in a plaque reduction assay. Accordingly, the designation 99011475 refers to the reference virus employed in plaque reduction assays and the avian reoviruses related antigenically thereto that are covered by the claim (such as those shown in Tables 2 and 3) and those that induce antiserum that causes significant (at least 75%) plaque reduction of the reference virus.

Furthermore, as is taught by the specification, considerable antigenic heterogeneity exists between avian reoviruses (page 4, lines 1-7) and embodiments of the

present invention, the new antigenic class of avian reoviruses. The prior art document accompanying this Response by Nersessian et al. (J. Vet. Res. N50, 1989, pp. 1475-1480) confirms this stated heterogenic immunological character of avian reoviruses and further validates the use of plaque reduction assays for determining and characterizing antigenic relationships (including, but not limited to, similarities and differences) between reovirus isolates on page 1475, right column, first full paragraph. Accordingly, Applicants use of the plaque reduction assay for characterization of the present invention is an art-accepted manner of characterizing (reoviruses, i.e., one skilled in the art would not find the claim language vague and/or indefinite.

Claims 5-9 further stand rejected under §2 as being vague and indefinite for the use of the term "one or more vaccine components." Applicants respectfully request reconsideration of the rejection. Applicants have defined "one or more vaccine components" on page 11, lines 17-21 as other pathogens that are infectious to poultry which are antigenically distinct from the avian reoviruses of the present invention. Applicants further respectfully request reconsideration of the rejection on the grounds that it is common in the art of vaccines, especially poultry vaccines, for more than one virus component to be present in a vaccine. Therefore, the use of the term, "one or more vaccine components" is not vague and indefinite and would be understood by one of ordinary skill in the art.

As evidence of art acceptance and understanding of the term "one or more vaccine components," Applicants are enclosing a copy of pages from a Product Guide from July of 1998. Applicants have included a copy of the front cover, the back cover

and a page detailing combination vaccines. As can be seen, COMBOVAC-30 is a lyophilized vaccine containing the Clone-30 strain of Newcastle disease virus and regular Massachusetts (Connaught strain) and Connecticut types of infectious bronchitis viruses. Therefore, the term "one or more vaccine components" is not vague or indefinite in this art field. Accordingly, Applicants respectfully request removal of the rejection.

Applicants have added a new Claims 16 and 17 that specifically claims various exemplary vaccine components and further define the vaccine components. Such components are not intended to be limiting.

Applicants have added new Claims 18-23 to Claim further elected embodiments of the present invention.

#### B. 35 USC §112, 1<sup>st</sup> ¶

Claims 5-9 and 14 stand rejected under 35 USC §112, 1<sup>st</sup> ¶, as failing to provide an enabling disclosure for the claimed invention. Applicants have submitted the declaration of the attorney for Applicant, William P. Ramey, III. Such declaration fully complies with the requirements. Accordingly, Applicants respectfully request reconsideration of the rejection in light of this response and the declaration.

#### IV. Conclusion

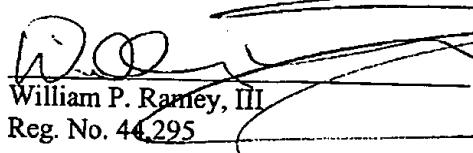
Applicants respectfully request reconsideration of the rejections in light of this response. The application is believed in a condition for allowance and Applicants respectfully request such action. Please call the below undersigned attorney for any

assistance in securing allowance of this application and for an interview if the Examiner considers an interview beneficial. Please charge deposit account number 02-2334 for any required fees.

Date:

8/15/02

Sincerely,

  
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